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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/309,199 05/10/99 ASSENMACHER M 212302000720

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EXAMINER

VANDER VEGT, F

ART UNIT

PAPER NUMBER

1644.

12

DATE MAILED:

05/08/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/309,199

Applicant(s)

Assemacher et al

Examiner

F. Pierre VanderVegt

Art Unit

1644



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Feb 16, 2001
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-73 ~~is/are~~ pending in the application.
- 4a) Of the above, claim(s) 51-73 ~~is/are~~ withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-50 ~~is/are~~ rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892) 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 19) ☐ Notice of Informal Patent Application (PTO-152)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 20) ☐ Other: _____

DETAILED ACTION

This application claims priority to provisional application 60/085,136.

Claims 1-73 are currently pending in this application.

Election/Restriction

1. Applicant's election without traverse of Group I, claims 1-50, drawn to a method for preparing and/or detecting surface-modified antigen-specific T cells, in Paper No. 8 is acknowledged.

Claims 51-73 stand withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions. Election was made **without** traverse in Paper No. 8.

2. In view of the amendment filed February 16, 2001, only the following rejections are maintained.

Claim Rejections - 35 USC § 112

3. Claims 1-50 stand rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the claimed method when using a high viscosity or gel forming medium such as gelatin or agarose or alginate, does not reasonably provide enablement for the claimed method absent the use of said ingredients. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

It was stated previously: "Briefly, the claims are drawn to obtaining an enriched population of antigen-specific T cells based upon the production of response indicators and capture on the cell surface. The claims are not enabled for the identification for identifying such a population of T cells. The Manz et al reference, which includes the instant inventors among it's authors, (3 on form PTO-1449 filed 12/21/1999) discloses, "In normal medium the secreted product will readily diffuse away and, in the approach described here, will label all cells covered with the affinity matrix, whether they are secreting or not" (page 1923, first column in particular). Manz et al further discloses that a solution to this problem is to perform the assay in a high viscosity media (page 1923, first column in particular). Manz et al broadly characterizes the disclosed method in stating: "Crossfeeding of the secreted products to other cells is prevented by

decreasing the permeability of the incubation media" (see Abstract in particular). Manz et al thus discloses that there is a need for high viscosity media to practice the instant invention. The instant specification does not disclose conditions under which the high viscosity medium requirement can be overcome. Therefore, the enablement provided by the instant specification is not commensurate with the scope of claims that do not recite the aforementioned ingredients as a component of the claimed method.

In view of the quantity of experimentation necessary, the unpredictability of the art, the lack of sufficient guidance in the specification and the breadth of the claims, it would take undue trials and errors to practice the claimed invention and this is not sanctioned by the statute."

Applicant's arguments filed February 16, 2001 have been fully considered but they are not persuasive.

Applicant contends that the claimed invention is fully enabled for the practice of the claimed method in any type of medium. Applicant contends that high-viscosity medium is merely an optional embodiment, not a requirement for practice, alluding to the specification at page 35, lines 11-26. It is respectfully submitted that merely stating something is part of the invention does not constitute an enabling disclosure. The specification does not teach any method of overcoming the need taught by the prior art to use a medium which limits the ability of the secreted molecules to diffuse away from the intended capture cells. Applicant asserts that the example in the specification at page 46, lines 1-5, was performed without the use of high viscosity medium, however, there is absolutely nothing in the passage which gives any indication regarding the composition, or viscosity, of the medium. Accordingly, in the absence of objective evidence to the contrary, the rejection must be maintained.

Conclusion

4. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

5. Papers related to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. Papers should be faxed to Group 1640 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The fax phone number for official documents to be entered into the record for Art Unit 1644 is (703)305-3014.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to F. Pierre VanderVegt, whose telephone number is (703)305-6997. The Examiner can normally be reached Tuesday through Friday and odd-numbered Mondays (on year 2001 365-day calender) from 6:30 am to 4:00 pm ET. A message may be left on the Examiner's voice mail service. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Ms. Christina Chan can be reached at (703)308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist, whose telephone number is (703)308-0196.

F. Pierre VanderVegt, Ph.D.
Patent Examiner
Technology Center 1600
May 7, 2001

CHRISTINA Y. CHAN
SUPERVISORY PATENT EXAMINER
GROUP 1800-1640